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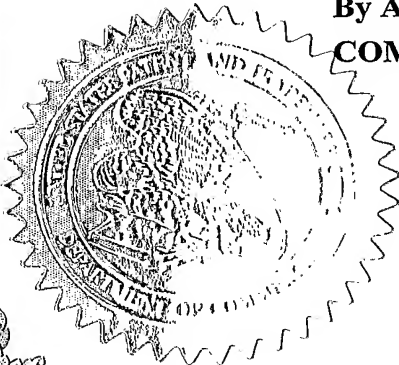
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APPLICATION NUMBER: 60/570,469

FILING DATE: May 13, 2004

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| INVENTOR(S)                            |                        |   |
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| Given Name (first and middle (if any)) | Family Name or Surname | Residence<br>(City and either State or Foreign Country) |
| ELAN                                   | ZIV MD                 | RAMAT GAN ISRAEL  |

Additional inventors are being named on the \_\_\_\_\_ separately numbered sheets attached hereto

| TITLE OF THE INVENTION (500 characters max)  |                        |
|--|------------------------|
| A FLEXIBLE MID-URETHRAL SUPPORT DEVICE FOR THE TREATMENT AND PREVENTION OF URINARY INCONTINENCE IN FEMALES |                        |
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| OR   |               |           |                 |
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## ENCLOSED APPLICATION PARTS (check all that apply)

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| <input checked="" type="checkbox"/> Specification Number of Pages | 7 | <input type="checkbox"/> CD(s), Number   |  |
| <input checked="" type="checkbox"/> Drawing(s) Number of Sheets   | 6 | <input type="checkbox"/> Other (specify) |  |
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[Page 1 of 2]

Respectfully submitted,

 SIGNATURE ELAN ZIV MD  
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 Date 30.4.04  
 REGISTRATION NO. \_\_\_\_\_  
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☒ Applicant claims small entity status. See 37 CFR 1.27

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(\$)  
80**Complete if Known**

Application Number

Filing Date

MAR 14 15 2004 May 11 2004

First Named Inventor

Dr Elan Ziv

Examiner Name

Art Unit

Attorney Docket No.

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| Large Entity<br>Fee Code (\$) | Small Entity<br>Fee Code (\$) | Fee Description        | Fee Paid |
|-------------------------------|-------------------------------|------------------------|----------|
| 1001 770                      | 2001 385                      | Utility filing fee     |          |
| 1002 340                      | 2002 170                      | Design filing fee      |          |
| 1003 530                      | 2003 265                      | Plant filing fee       |          |
| 1004 770                      | 2004 385                      | Reissue filing fee     |          |
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80**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

|                    |  |         |  |   |  |   |  |
|--------------------|--|---------|--|---|--|---|--|
| Total Claims       |  | -20** = |  | X |  | = |  |
| Independent Claims |  | -3** =  |  | X |  | = |  |
| Multiple Dependent |  |         |  |   |  | = |  |

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| 1202 18                       | 2202 9                        | Claims in excess of 20                                     |
| 1201 88                       | 2201 43                       | Independent claims in excess of 3                          |
| 1203 290                      | 2203 145                      | Multiple dependent claim, if not paid                      |
| 1204 88                       | 2204 43                       | ** Reissue independent claims over original patent         |
| 1205 18                       | 2205 9                        | ** Reissue claims in excess of 20 and over original patent |

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|---------------|---------------|--|----------|
| 1051 130      | 2051 65       | Surcharge - late filing fee or oath  |          |
| 1052 50       | 2052 25       | Surcharge - late provisional filing fee or cover sheet                     |          |
| 1053 130      | 2053 130      | Non-English specification  |          |
| 1812 2,520    | 1812 2,520    | For filing a request for <i>ex parte</i> reexamination                     |          |
| 1804 920*     | 1804 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805 1,840*   | 1805 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251 110      | 2251 55       | Extension for reply within first month                                     |          |
| 1252 420      | 2252 210      | Extension for reply within second month                                    |          |
| 1253 950      | 2253 475      | Extension for reply within third month                                     |          |
| 1254 1,480    | 2254 740      | Extension for reply within fourth month                                    |          |
| 1255 2,010    | 2255 1,005    | Extension for reply within fifth month                                     |          |
| 1401 330      | 2401 165      | Notice of Appeal   |          |
| 1402 330      | 2402 165      | Filing a brief in support of an appeal                                     |          |
| 1403 290      | 2403 145      | Request for oral hearing   |          |
| 1451 1,510    | 1451 1,510    | Petition to institute a public use proceeding                              |          |
| 1452 110      | 2452 55       | Petition to revive - unavoidable   |          |
| 1453 1,330    | 2453 665      | Petition to revive - unintentional   |          |
| 1501 1,330    | 2501 665      | Utility issue fee (or reissue)   |          |
| 1502 480      | 2502 240      | Design issue fee   |          |
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| 1460 130      | 1460 130      | Petitions to the Commissioner  |          |
| 1807 50       | 1807 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806 180      | 1806 180      | Submission of Information Disclosure Stmt                                  |          |
| 8021 40       | 8021 40       | Recording each patent assignment per property (times number of properties) |          |
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Date March 14, 2004

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## **A FLEXIBLE MID-URETHRAL SUPPORT DEVICE FOR THE TREATMENT AND PREVENTION OF URINARY INCONTINENCE IN FEMALES**

The present invention relates generally to the field of treatment of urinary incontinence in female patients. More specifically, the present invention relates to a disposable device for use in the treatment of urinary incontinence in women. The invention describes a vaginal disposable device which is inserted and removed in a no-self-touch technique, by the patient herself, using a disposable applicator.

**Inventor:** Dr Elan Ziv, MD OBGYN, Urogynecologist

### **Background of the Invention**

Urinary incontinence is a widespread problem among females. It is estimated that up to 50% of women occasionally leak urine involuntarily, and that approximately 25% of woman will seek medical advice at some point in order to deal with the problem. Stress incontinence, the most common type of urinary incontinence, refers to the involuntary loss of urine resulting from abdominal pressure rise, occurring during exercise, coughing, sneezing, laughing, etc. When stress incontinence occurs, it is usually the result of the abnormal descent of the urethra and bladder neck below the level of the pelvic floor. While many different factors may contribute to the development of stress incontinence, it is most prevalent among women ages 35-65 and those who have had multiple vaginal deliveries. Stress incontinence is both aggravating and unpleasant for women, and it can also be embarrassing. Many women wear sanitary pads or diapers in order to deal with incontinence, though this is not a real solution to the problem and it can be very inconvenient and unreliable. Surgical treatment may involve securing the paraurethral tissues to the periosteum of the pubic bone or the rectus facia in order to elevate the bladder neck above the pelvic floor and thereby distribute pressure equally to the bladder, the bladder neck, and the mid-urethra. Recently, a procedure known as "TVT" ("Tension Free Vaginal Tape") was developed, in which a mesh tape is implanted underneath mid-urethra, creating a hammock on which the urethra may kink during physical effort.

However, surgery is only suitable for severe cases, and the majority of women experiencing incontinence do not need surgical solutions.

One modality of non-surgical treatment involves the use of devices that are inserted into the vagina, either by a medical practitioner or by the woman herself. Most devices are designed to apply pressure against the bladder neck so as to inhibit or completely block the flow of urine through the urethra. A variety of such devices are known in the art. For example, refer to U.S. Patent No. 5,618,256 to Reimer, entitled, "Device for Arrangement in the Vagina for Prevention of Involuntary Urination with Females and an Applicator for use in Insertion of the Device;" U.S. Patent No. 5,785,640 to Kresch, entitled "Method for Treating Female Incontinence;" U.S. Patent No. 4,920,986 to Biswas, entitled, "Urinary Incontinence Device;" U.S. Patent 5,417,226 to Juma, entitled, "Female Anti-Incontinence Device;" U.S. Patent No. 5,386,836 to Biswas, entitled, "Urinary Incontinence Device;" and U.S. Patent No. 5,007,894 to Enhorning, entitled, "Female Incontinence Device."

The existing non-surgical incontinence devices suffer from numerous drawbacks:

- A number of devices are constructed so as to completely block the urethra and thus they need to be removed or collapsed in order to allow the woman to urinate, an inconvenience for the woman wearing the device.
- To overcome this drawback, vaginal devices have been developed having specialized shapes that do not completely block the bladder neck. These devices tend to be large, uncomfortable, and intrusive. They also tend to cause irritation or soreness to the vagina.
- Such devices are expensive to manufacture, and therefore, they are designed to be reusable and/or to remain in the vagina for an extended period of time. Such devices are normally made from large bodies of resilient material, such as plastic or hard rubber, in order to preserve their functioning for the required amount of time.
- Most devices known in the art also tend to be difficult or painful to insert and/or remove. In order to correctly inhibit urine flow, the device needs to be properly positioned in the vaginal canal. As stated previously, a doctor may be required to properly position the device.

- In cases where a doctor has to insert the device, the device is adapted for remaining in the vagina for a prolonged period of time. When positioned in the vagina for an extended period of the time, the device may cause vaginal infections, necrosis, or bleeding.
- 5 • The device may block or inhibit the flow of normal body secretions through the vagina, and may cause inflammation of the vagina and a foul-smelling discharge.
- In cases where the device is designed to be inserted by the woman herself, the device often has to be removed, cleaned, and then re-inserted after a predetermined number of hours.

10

All vaginal devices so far described or marketed have at least one of the limiting features described above. No vaginal device for controlling urinary incontinence has so far been successfully marketed and used by the woman herself. There is a need for a device for controlling involuntary urination that is disposable, easy and comfortable for a woman to use, that works effectively and reliably, and that is completely sanitary and hygienic.

15

### **The Invention**

The present invention provides a device for the treatment of urinary incontinence females. The device of the present invention is adapted to be disposable, worn only for a maximum of 16 hours and then discarded and replaced with a new device (if needed).

5 The device of the present invention is simple and easy to use, and is inserted effortlessly in the same user-friendly and familiar manner that a tampon is inserted into the vagina during menstruation. As opposed to large and intrusive devices of the prior art, the device of the present invention is comfortable, and, once inserted, the woman need not think about it again until it is removed.

10 When involuntary urination occurs, it is usually the result of the abnormal descent of the bladder neck and the urethra into a low position, away from the intra-abdominal pressure system. This "hypermobility" is the result of some injury to the support mechanism which normally keeps the urethra and the bladder neck in a raised position, along the backside of the pubic bone. The lowering of the bladder neck and the urethra that occur,  
15 for example, when a woman coughs, sneezes, or laughs, causing involuntary leakage of urine. The device of the present invention is designed so as to provide a "cradle" or shelf-like support to the urethra whenever the urethra descends momentarily, so as to prevent the leakage of urine. The device does not put pressure against the urethra or the bladder neck, but only provides support when there is a rise in abdominal pressure.

20 The present invention relates to a disposable device for the prevention of involuntary urination in females, adapted for being inserted into the vagina, comprising;

- (a) an internal support structure
- (b) a cover covering said internal support structure and comprised of a flexible  
25 material, and;
- (c) an applicator coupled to the internal support structure and the cover for facilitating insertion of the device into the vagina;

The main device and the cover are adapted for forming a cradle support for the mid-urethra following insertion of the device into the vagina so as to prevent involuntary  
30 urination while allowing for voluntary urination.



The invention will now be described with reference to accompanying drawings:

FIG. 1A is a side view of the internal support structure.

FIG. 1B is a top view of the internal support structure

FIG. 1C is a bottom view of the internal support structure

5 FIG. 2A is a perspective view of the covering

FIG. 2B is a perspective view of the main device inside the covering.

FIG. 3 is a perspective view of the applicator.

FIG. 4 is a sectional view of the invention within the applicator

FIG. 5 is a side view of the female pelvis.

10 FIG. 6 is another embodiment of the device with different shapes and curves of the arms.

The core of the device is a one prolonged embodiment (FIG 1A) which has three distinct parts:

- 15
1. A top section (12) which serves as the "anchoring" element, for stabilizing the device within the vagina,
  2. A bottom section (14) which serves as the "supporting" element, generating mid-urethral support,

Each element of the device (FIG 1A+B+C) has 4 flexible arms. These arms of the  
20 anchoring element (12), force the device to remain in situ within the vagina, unable to move inwards or outwards, or to rotate. This occurs as a result of the special tendency of vaginal walls to collapse and form an occluded lumen. The flexible arms of the device cause "tenting" of the walls on top of them with resultant sagging of the walls around the intermediate section, thereby stabilizing the device. The arms of the supporting element  
25 (14) cause elevation of the tissues around mid-urethra, acting as a hammock. This hammock supports mid-urethra in a tension free manner, much like the TVT operation.

The device is introduced into the cover (FIG 2).

Another embodiment of the device, with different shapes and curves of the arms is shown in FIG 6.

The cover (FIG 2A) is made of a flexible smooth mesh material (16) designed as small sack with a string (18). FIG 2B shows the device (20) within the tightly closed mesh cover (22). The cover allows for:

- Reduction of the friction between vagina and the device during insertion & removal.
- 5 • Reduction of the friction between the applicator and the device during insertion.
- Pulling the string causes straightening of the cover, straightening of the vaginal walls, allowing for an easy and smooth removal of the device from the vagina.
- Pulling the string causes the arms to fold slightly towards the midline, thereby reducing its size, allowing for an easy and smooth removal of the device from the vagina.
- 10 • The mesh of the cover, being stretched between the arms of the device, also serve as a hammock. In a woman who leaks urine during a stressful event (when abdominal pressure rises during coughing, sneezing, etc.), the urethra sags down but meets the hammock in its mid part. That also causes an elevation of the intra urethral pressure
- 15 with resultant urinary continence.

The applicator serves for insertion of the device into the vagina (FIG 3), as is done when inserting a regular menstrual tampon. The device is kept within the wider part (26) that is inserted into the vagina. When pushing the plunger (28), the device is pushed through the flower like opening (24), allowing for its immediate action once the applicator is removed from the vagina. The string (32) is visible, protruding out of the opening of the plunger (30).

When the device is still within the applicator (FIG 4), its flexible arms (34) converge towards the midline, allowing for the small dimensions and its insertion via a small diameter applicator. After insertion (FIG 5), the flexible arms of the device gain their pre-intended tension, enlarge the diameter of the device (46) within the vagina (48), anchoring itself under the bladder (40) between the uterine cervix (36) and the pubic bone (38), supporting mid-urethra (42). The string protrudes out of the vaginal introitus (44), as with the regular menstrual tampon, allowing for removal.

The invention has in its basic concept the following features:

- Being a disposable device.
- Insertion of the device is always with an applicator.
- Easy & comfortable insertion and removal.
- 5   • Being comfortable to wear.
- Being hygiene & odorless
- Being a familiar procedure to most female patients – as inserting a menstrual tampon.
- Being inserted by the patient herself, in a no-self-touch technique, with a
- 10   disposable inserter.
- Being removed by the patient herself, in a no-self-touch technique, with the device collapsing and becoming of small size for painless removal.
- Being of high availability, easy to get everywhere, sold as an Over the Counter (OTC) device.
- 15   • Being of low cost.
- Having complete confidentiality, as with the use of menstrual tampons.
- Having the ability to be removed instantly when needed.
- No blockage of vaginal discharge.
- Wide range of diameters

**Alternative embodiments of the invention.**

- It may be manufactured in different sizes
- It may be made of many flexible materials, such as silicone, polyurethane, etc.
- 25   • It can have more or less than 4 arms.
- The angle between the arms may be changed.
- Shape and curves of the arms may vary

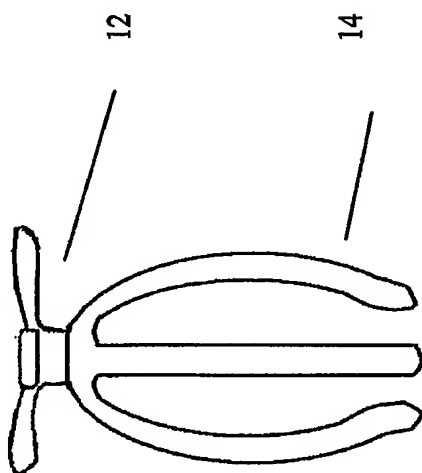


FIG. 1A

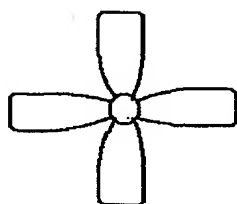


FIG. 1C

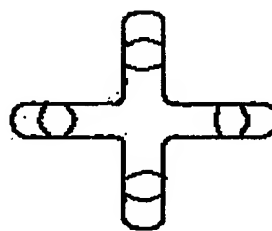
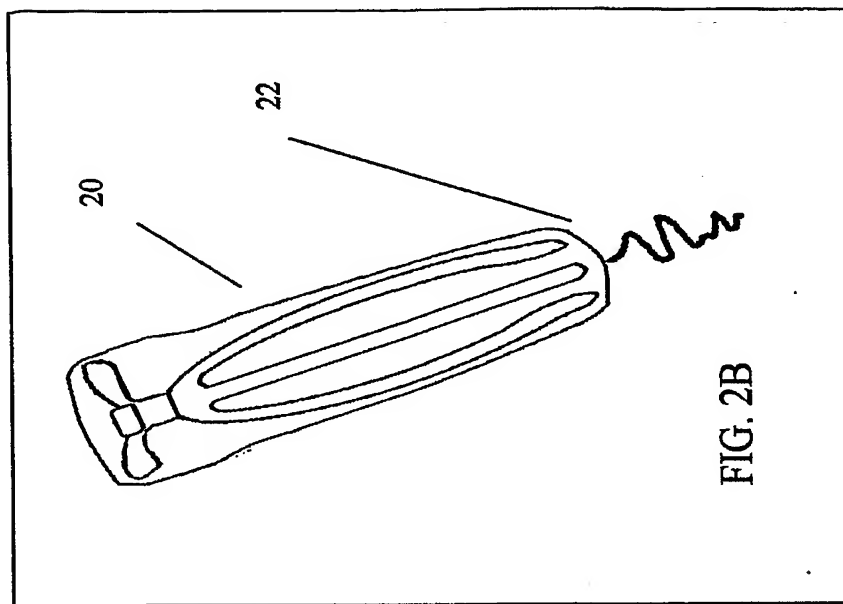
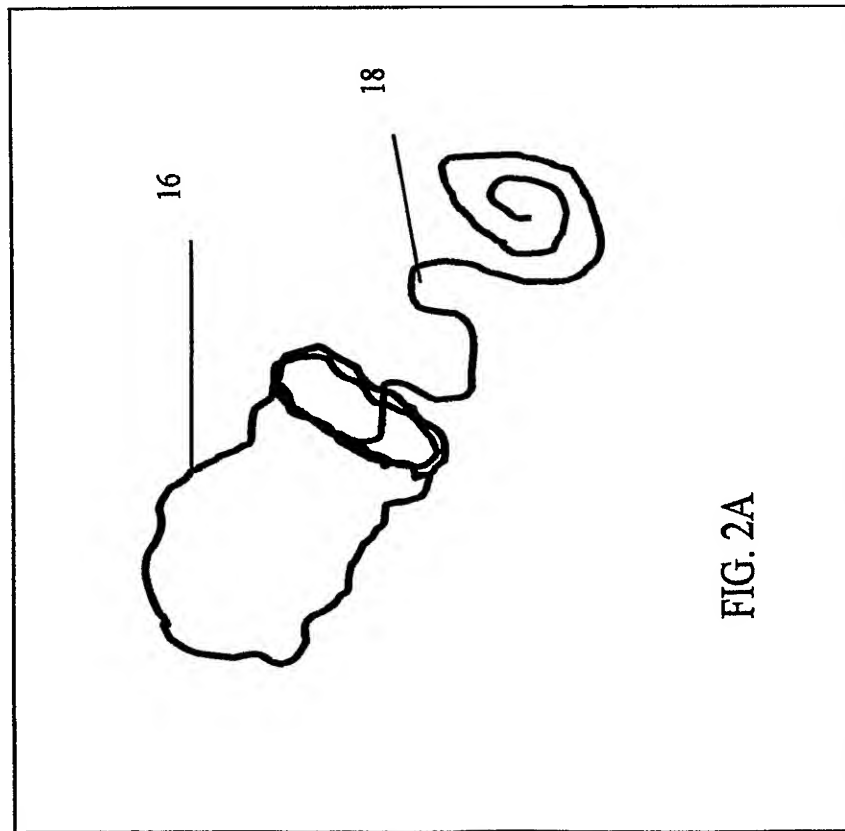
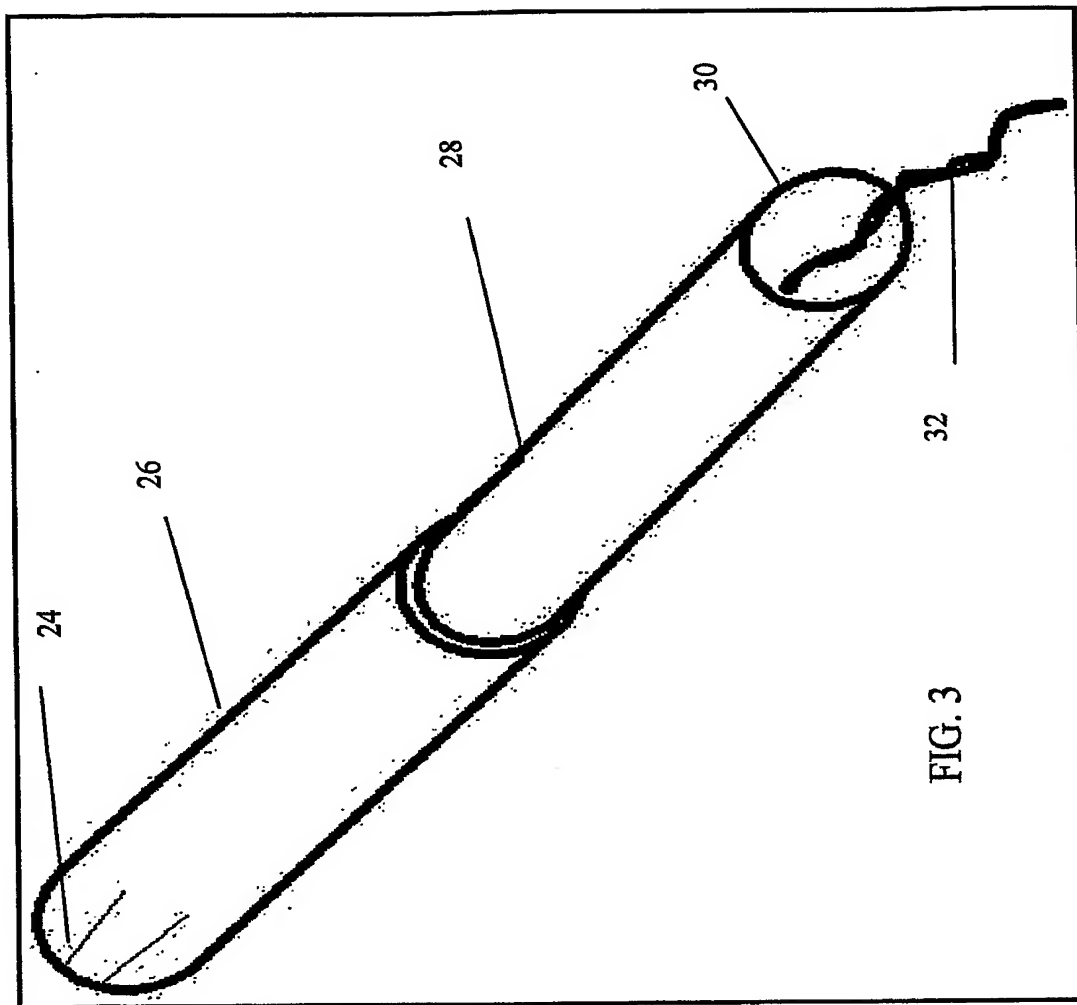


FIG. 1B

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"  
Dr Elan Ziv, MD, OBGYN, Urogynecologist



"A flexible midurethral support device for treatment & prevention of female urinary incontinence"  
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"A flexible midurethral support device for treatment & prevention of female urinary incontinence"  
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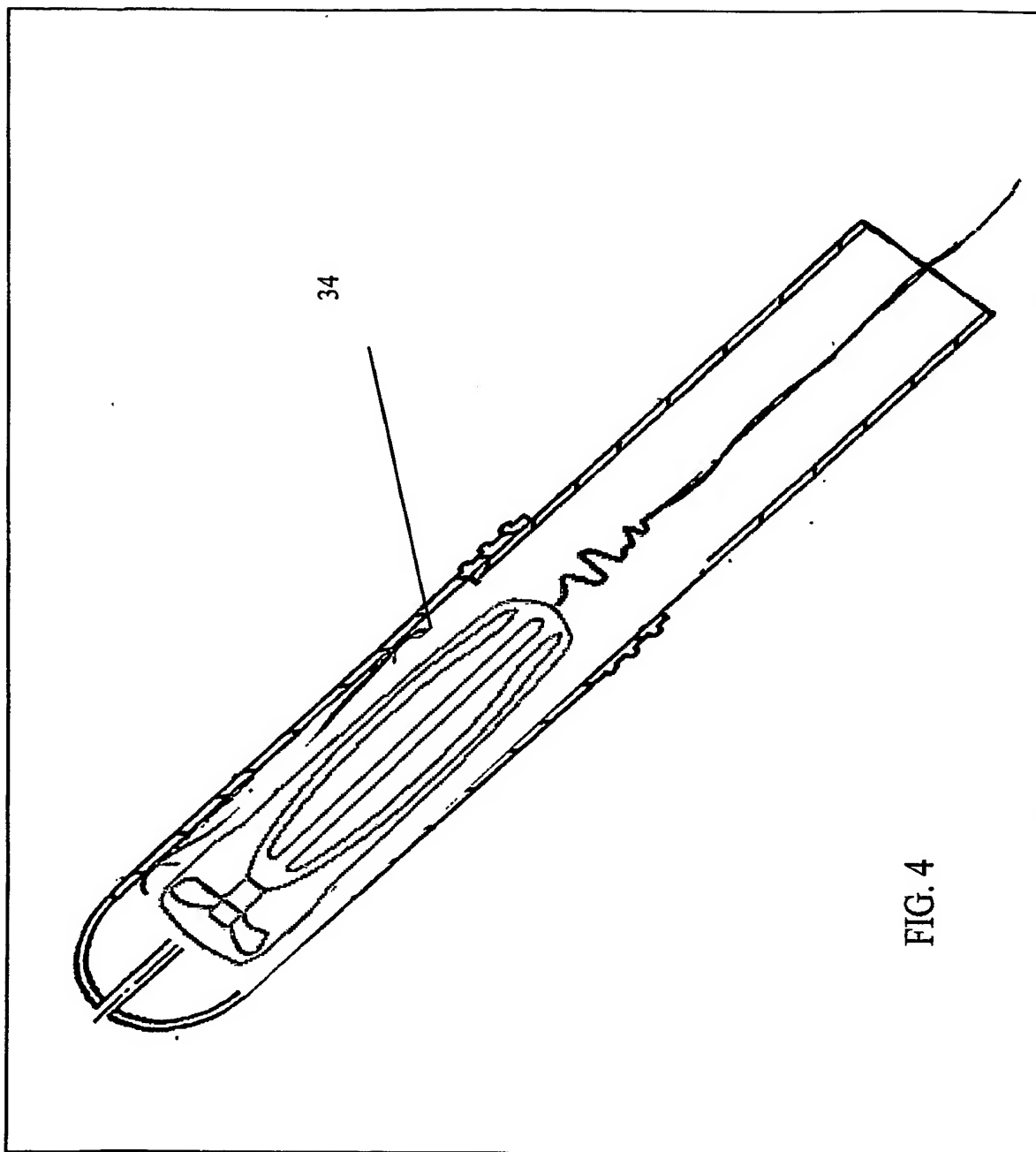
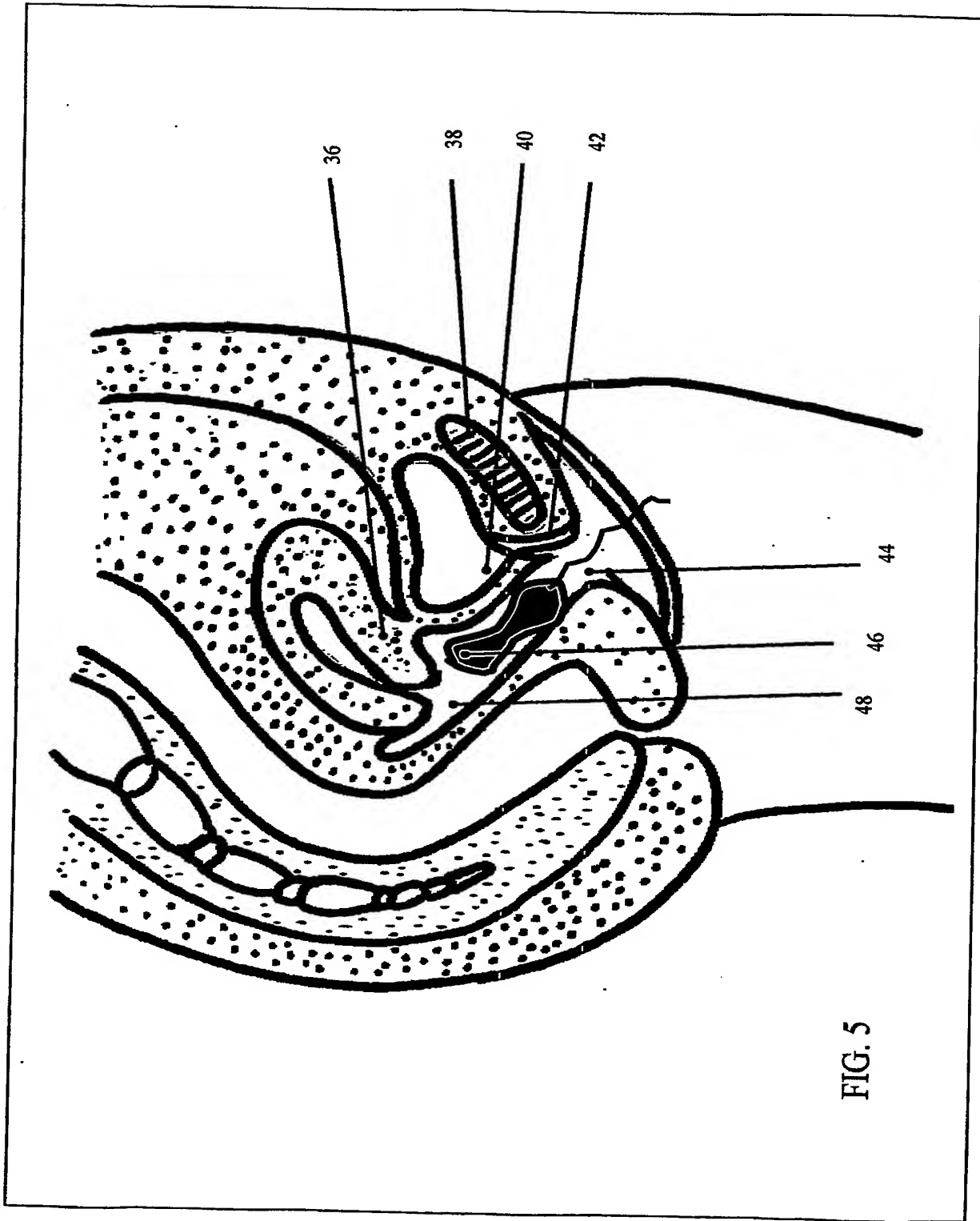


FIG. 4

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"  
Dr Elan Ziv, MD, OBGYN, Urogynecologist



"A flexible midurethral support device for treatment & prevention of female urinary incontinence"  
Dr Elan Ziv, MD, OBGYN, Urogynecologist



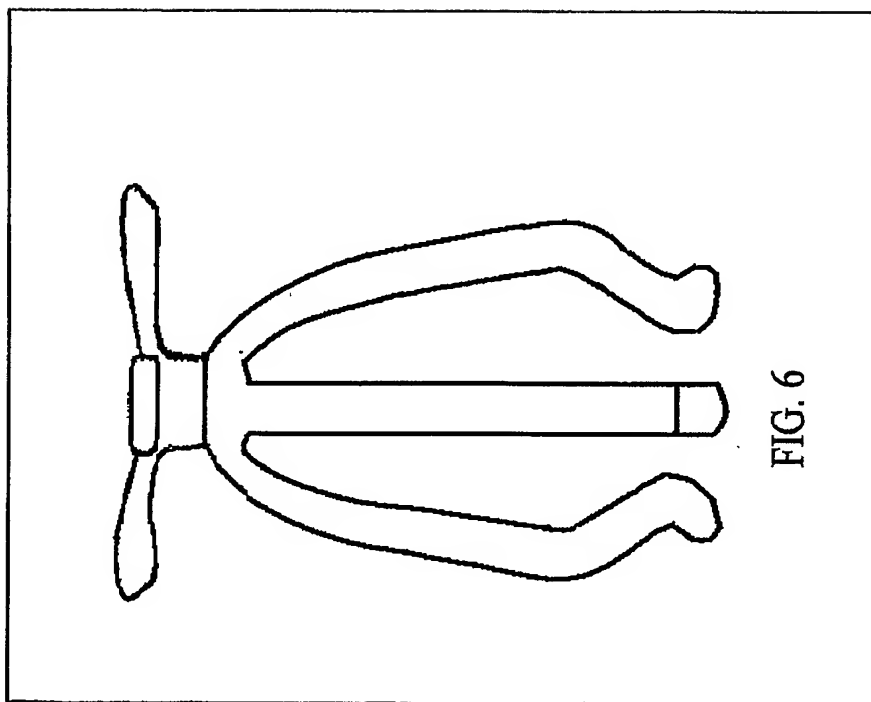


FIG. 6

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"  
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